DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

June 15, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eddie S. Schaap
Owner
North Point Dairy
2149 Curry Road H
Clovis, NM 88101

Ref. #: DEN-01-36

Dear Mr. Schaap:

Consumer Safety Officer Betty K. Baxter conducted an investigation at your dairy farm located in Clovis, New Mexico on April 17, 2001. The inspection confirmed that you offered an animal for sale for slaughter as food in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On November 13, 2000, you offered a cow for slaughter as human food to [xxxxxx xxxx] [xxxxx]. This cow, identified as USDA case number 00-0471-NM, was found with illegal levels of drug residue.

Specifically, USDA analysis of tissue samples collected from cow #6632, on November 13, 2000, identified the presence of sulfadimethoxine residue of 0.36 ppm in the liver and 0.34 ppm in the muscle. A tolerance of 0.10 ppm has been established for residues of sulfadimethoxine in the edible tissues of beef cows in Title 21 Code of Federal Regulations Part 556.640 (21 CFR 556.640).

Our investigation revealed the use of Pfizer Animal Health Albon Sulfadimethoxine injection. The presence of this drug at the levels found in edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions which are inadequate to prevent medicated animals bearing potentially harmful drug residues from entering the food supply. For example, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the Act.

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The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt and permanent action to correct the above violations and to establish procedures whereby such violations do not recur. This is the second Warning Letter issued to you for tissue residue violations in less than one year. You were issued a Warning Letter on August 9, 2000 for illegal penicillin residues in one of your cows. We consider this second violation to be a very serious matter. Failure to make lasting corrections will result in regulatory action without further notice including seizure, prosecution, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Tom Warwick, Compliance Officer, U.S. Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,

Paul J. Tetell for
Thomas A. Allison
District Director

cc: Mr. Ronald K. Jones
D.V.M.
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

cc: [XXXX]

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